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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,371	01/16/2007	Alan Cuthbertson	PZ0382	3817
36335	7590	11/02/2010	EXAMINER	
GE HEALTHCARE, INC. IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231			RIDER, LANCE W	
			ART UNIT	PAPER NUMBER
			1618	
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			11/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,371	CUTHBERTSON ET AL.	
	Examiner	Art Unit	
	LANCE RIDER	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 August 2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
 4a) Of the above claim(s) 3,5,7-15,18,20,22-28,32 and 34-36 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,2,4,6,16,17,19,21,29,30 and 33 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/20/2010</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of the Application

The remarks and amendments filed on August 24th 2010 are acknowledged.

Claims 1-32 are pending and claims 3, 5, 7-15, 18, 20, 22-28, 32, and 34-36 have been withdrawn by applicant.

Response to arguments

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4, 6 16-17, 19, 21, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahagan et al., European Patent Application EP 1088550 A1, provided in the IDS.

This rejection is MAINTAINED for the reasons of record set forth in the office action mailed on March 25th 2010 and for the reasons set forth below. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues "Sahagan teaches methods of treatment using various labeled compounds and drug biodistribution studies. Sahagan is silent on medical imaging, let alone the PET and SPECT imaging of the present claims."

In response to this argument, applicant's claims are drawn to compounds and not methods of imaging. Sahagan teaches specific compounds which fall entirely inside applicants' instantly claimed Markush of compounds. Sahagan explicitly states that "isotopically-labeled compounds, which are identical to those recited in formula (I), but for the fact that one or more atoms are replaced by an atom having an atomic mass or mass number different from the atomic mass or mass number usually found in nature"

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are part of his invention and explicitly includes the isotope ^{18}F . There is only one fluorine atom found in the example compound of Sahagan, thus the artisan would immediately envisage placing ^{18}F there. Applicant also seems to interpret Sahagan as explicitly stating to use only ^3H or ^{14}C in the compounds, which is not true. Sahagan explicitly states “Compounds relating to the present invention, prodrugs thereof, and pharmaceutically acceptable salts of said compounds or of said prodrugs which contain the aforementioned isotopes and/or other isotopes of other atoms are within the scope of this invention” and all of his further comments are related to non-limiting examples of how to use such compounds, such as in tissue distribution assays, thus his use of the term “for example”.

Applicants also argue “if Sahagan is properly construed, in the absence of the teaching of the present invention, and in the light of the common general knowledge of the person skilled in the art, any motivation it provides towards tissue distribution assays teaches towards ^3H and/or ^{14}C , not ^{18}F . Thus, the Examiner's alleged motivation in this regard does not actually exist.”

In response to this argument, Sahagan teaches isotopically labeling his compounds with ^{18}F and using isotopically labeled compounds in tissue distribution studies. Though applicant tries to support their above arguments by stating that PET and SPECT are not distribution assays and ^{18}F is not a plausible distribution assay isotope, the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). In order to promote compact prosecution of the case the examiner is providing evidence (the included

Pochapsky reference) to refute applicant's statements. Pochapsky teaches using ¹⁸F labeled compounds in tissue distribution assays. (See title.) Pochapsky also teaches that PET and SPECT are tissue distribution assays. (See page 231, paragraph 2.) Thus, in the absence of the teaching of the present invention, and in the light of the common general knowledge of the person skilled in the art, one of ordinary skill in the art would have understood Sahagan's example to be non-limiting and that ¹⁸F was useful in tissue distribution assays such as PET and SPECT.

Claims 1-2, 4, 6 16-17, 19, 21, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahagan et al., European Patent Application EP 1088550 A1 (provided in the IDS), in view of Wilbur, D.,S., (Bioconjugate Chemistry, 1992).

This rejection is MAINTAINED for the reasons of record set forth in the office action mailed on March 25th 2010 and for the reasons set forth below. Applicant's arguments have been fully considered but they are not persuasive.

Applicants stress the argument that PET and SPECT are not tissue distribution assays.

In response to this argument, the claims are drawn to compounds and the Pochapsky reference provided as evidence teaches that PET and SPECT are tissue distribution assays.

Applicants argue that Sahagan teaches isotopically labeling the compounds by exchanging an atom not by adding an atom and Wilbur is drawn only to labeling proteins and peptides and not small molecules, thus the references are not combinable

since Sahagan refers to molecules outside the scope of the molecules radiolabelled by Wilbur.

. In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Sahagan states that radiolabeled versions of the metalloproteinase inhibitors would be useful for tissue distribution assays. Wilbur provides a method to radiolabel compounds so they can be imaged using PET (a tissue distribution assay). Both Wilbur and Sahagan teach radiolabeling small molecules, both teach radiohalogenating the compounds, and both teach labeling the compounds to use them in tissue distribution assays (such as PET). Wilbur teaches labeling methods and reagents for conjugate labeling of both proteins and many different small molecules. (See title, page 434 paragraph 5 line 9, page 437 paragraph 4, etc.) Wilbur teaches labeling small molecules such as lactitol dilactitol, etc., with the general radioalkylating agent ¹²³I-tyramine, contrary to applicant's assertion that Wilbur only teaches labeling proteins. (See page 460 paragraph 4 as cited in the previous action.) Using a common radiohalogenating

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agent to radiolabel compounds which are taught to be radiohalogenated would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sahagan et al., European Patent Application EP 1088550 A1 (provided in the IDS) and of Wilbur, D.,S., (Bioconjugate Chemistry, 1992) as applied to claims 1-7, 12, 14-19, 21, and 29-32 above, and further in view of Fruchtel, J.S., (Angew. Chem. Int. Ed. Engel., 1996).

This rejection is MAINTAINED for the reasons of record set forth in the office action mailed on March 25th 2010 and for the reasons set forth below. Applicant's arguments have been fully considered but they are not persuasive.

Applicants argue that the references of Sahagan and Wilbur do not render the invention obvious, thus the addition of the Fruchtel reference cannot render claim 33 obvious.

In response to this argument, the references of Sahagan and Wilbur teach making the instantly claimed compound, thus the reference of Fruchtel is properly added to show that solid phase organic synthesis was commonly used at the time of the invention including a solid phase support would have been obvious in order to automate synthesis of the compounds taught by Sahagan and Wilbur.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 12, 14-19, 21, and 29-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 10/544945.

This rejection is MAINTAINED for the reasons of record set forth in the office action mailed on March 25th 2010 and for the reasons set forth below. It is noted that applicants stated that a terminal disclaimer may potentially be filed if the instant application is found allowable.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LANCE RIDER whose telephone number is (571)270-1337. The examiner can normally be reached on M-F 11-12 and 1-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LANCE RIDER/
Examiner, Art Unit 1618

/Jake M. Vu/
Primary Examiner, Art Unit 1618